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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/610,339	06/30/2003	Robert R. Alfano	81424CIP	6566
23685 7590 07/27/2007 KRIEGSMAN & KRIEGSMAN 30 TURNPIKE ROAD, SUITE 9 SOUTHBOROUGH, MA 01772			EXAMINER CHAO, ELMER M	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 07/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/610,339

Applicant(s)

ALFANO ET AL.

Examiner

Elmer Chao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-29 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-29 and 31-37 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 June 2003 and 13 November 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

DETAILED ACTION

1. Acknowledgement is made of Applicants' Amendment filed 11/13/2006.
2. Acknowledgement is made of Applicants' Terminal Disclaimer filed 12/05/2006.

Response to Arguments

3. Applicants' arguments filed 11/13/2006 have been fully considered but they are not persuasive.

4. Regarding Applicants' arguments with respect to claims 5-9, 30-34 and 36, Examiner asserts that the combination of Cook et al. in view of Farkas et al. would be obvious to a person of ordinary skill in the art. Despite the differences cited by Applicants, the confocal lens system taught by Farkas et al. would still bring an advantage to the imaging system taught by Cook et al. in that a confocal lens system would enable desirable variable magnification of tissue within a body cavity (Farkas et al., Para [008]). The differences in illumination between the two systems are not essential to the use of a confocal lens system and the advantages therefrom can be applied to both Cook et al. and Farkas et al. as one of ordinary skill in the art would understand in light of the two references.

5. Regarding Applicants' arguments with respect to claims 1, 2, 19-20, 22-23, 26-27, 35, and 37 the reasoning stated above with respect to claims 5-9, 30-34 and 36 would apply to the newly amended claim 1 and all of its dependent claims.

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6. The double patenting rejections have been subsequently withdrawn in light of the Terminal Disclaimer filed 12/05/2006.
7. The grounds of rejection have been subsequently changed to reflect the changes in the amended claims filed 11/13/2006.
8. Regarding claim 37, a new grounds of rejection has been made as necessitated by amendment.

Drawings

9. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicants are given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

10. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings contain hand-written numerals. Applicants are advised to employ the services of a competent patent draftsman outside the Office,

as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Interpretation

11. **Claims 1, 7, 32, and 36** appear to be invoking 35 U.S.C. 112, sixth paragraph due to the use of means plus functional language. Therefore the claim is interpreted to include the limitations as described in the specification and their equivalents. The means for "transmitting the output" are interpreted to include both wired and wireless transmission and their equivalents. The means for "moving said optics" are interpreted to include a retractable mechanism and a movable platform and their equivalents.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 1, 3, 4, 6-18, 21, 24-26, 28, 29, 31-34, and 36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (U.S. 2002/0111546 A1) in view of Farkas et al. (U.S. 2004/0097790). Cook et al. teach an apparatus suitable for use in examining, for example the skin and mucosa, including a spectrometer for illumination of an object at one or more wavelengths (Para [0007]) in which each light source is

polarized (Para [0046]), as is known in the art. The orientation of the polarizer may be adjusted. It is taught that the light source may be a plurality of LEDs, each emitting a different wavelength of light, such as green, blue, and red, wherein the source may be configured, or controlled, to emit a particular wavelength of light by means of one or more LEDs (Para [0107]). Alternatively, the light may be a light bulb, which would provide white light, and a means of spectral selection such as a colored filter (Para [0007]), such as the red and green filters explicitly disclosed (Para [0100]). Light is used in both the visible and near infrared range (Para [0006]). A detector, such as a camera may be used to detect the light and capture an image. Optics, such as lenses are used in the system, and the illumination is detected by the image capturing device (Para [0016] & Para [0067]). Additionally, imaging optics such as magnifying optics may also be included (Para [0098]). A computer system is coupled to the image capturing means and carries out image processing steps (Para [0044]). The processing station also provides a display (Para [0175]). Memory is used which may be of many forms including a removable storage device (Para [0163]). The transmission from the light detector and the computer may either be wired (Fig. 12A) or wireless (Fig. 12B), wherein the wired system comprises a cable connected between the two devices. Use of the system for the purpose of detecting cancer and precancerous conditions is merely a statement of intended use and the system disclosed is inherently capable of performing this function.

Cook et al., as discussed above, substantially teach the invention as claimed, but fail to explicitly teach the use of confocal optics and moving said optics to permit a

variable lens distance. Farkas et al. teach an endoscope for examining tissue and further teach a movable lens system (Para [0015]) that provides the ability to image the surface or subsurface (Para [0013]). The lens tube is axially movable relative to the stage from a retracted position to an extended position (Fig. 5a & 5b). A confocal lens assembly is used in the housing to provide high resolution imaging of both the surface layer and the layers beneath the surface (Para [0013]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the claims of the prior patent in light of the teachings in the reference by Farkas et al. to include a moving lens system, as Farkas et al. teach it is desirable to have variable magnification of tissue within a body cavity (Para [0008]).

14. **Claims 2 and 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. in view of Farkas et al., further in view of Perkins et al. (U.S. 6,106,457).

Regarding **claim 2**, Cook et al. and Farkas et al., as discussed above, substantially teach the invention as claimed, but fail to teach the use of an LCD display. Cook et al. also teach a housing that contains the illuminating means and optics as discussed above. Perkins et al. teach a compact imaging system that includes an integral display (abstract) that may be an LCD screen (claim 61). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Cook et al. in view of Farkas et al. in light of the teachings in the reference by Perkins et al., as inclusion of an LCD screen on the instrument itself advantageously provides a more compact system.

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Regarding **claim 37**, Cook et al., Farkas et al., and Perkins et al. substantially teach the limitations as discussed above. Cook et al. and Farkas et al. fail to explicitly teach the housing being gun-shaped. However, in the field of optical imaging, Perkins et al. teach a gun shaped housing with a control mounted on the handle portion of the housing (Fig. 3a, Item 95). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a gun-shaped housing with a control mounted on the handle portion in order to improve the hand-holding ability and operation of the device (col. 10, line 64 – col. 11, line 2).

15. **Claims 19, 20, 22, 23, 26, and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. in view of Farkas et al. Cook et al., as discussed above, teach both the use of LEDs, such as red, green, and blue, and of a monochromatic white light with selectable filters, such as red and green. Cook et al. and Farkas et al. do not teach the use of white LEDs or the use of blue filters. It would be an obvious modification, based on the teaching of Cook to use a white LED and a blue filter, as Cook et al. teach the use of a variety of light sources including white, red, green, and blue lights. Additionally, Cook et al. teach the use of both LEDs and filters to provide desired wavelengths. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a white LED and the use of a blue filter to provide the full functionality taught by Cook et al. with each type of light source.

16. **Claim 35** is rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. in view of Farkas et al., further in view of Gorti (U.S. 5,954,658). Cook et al. and Farkas et al. substantially teach the invention as claimed including the use of polarized

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light. They fail to teach the use of depolarized light. Gorti also teaches a system for imaging at precise depths within a tissue. Gorti further teaches that it is known in the imaging art to pass light through a polarizer whose orientation may be adjusted to allow for polarized or depolarized light (col. 5, lines 51-55). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Cook et al. in view of Farkas et al. in light of the teachings in the reference by Gorti to include polarized and depolarized scattered light sampling to provide improved images of the target tissue.

Conclusion

17. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC
7/20/2007


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